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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q88617

Fabio STRADELLA, et al.

Appln. No.: 10/542,507

Group Art Unit: 3754

Confirmation No.: 5920

Examiner: Unknown

Filed: February 13, 2006

For: DOSAGE INDICATOR FOR A DEVICE DISPENSING A FLUID PRODUCT

**SUBMISSION OF INTERNATIONAL PRELIMINARY
EXAMINATION REPORT (IPER)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

For the Examiner's convenience, enclosed herewith is a copy of the English translation of the International Preliminary Examination Report (IPER). It is noted that the three references cited in the International Search Report were previously submitted to the U.S. Patent and Trademark Office with an Information Disclosure Statement on July 15, 2005, and are therefore not enclosed herewith.

Respectfully submitted,

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WASHINGTON OFFICE
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PCT

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(règles 44bis.3.c) et 72.2 du PCT)

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Référence du dossier du déposant ou du mandataire
VALS 882 B PCT

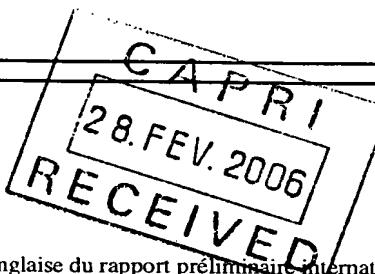
NOTIFICATION IMPORTANTE

Demande internationale n°
PCT/EP2004/000346

Date du dépôt international (jour/mois/année)
19 janvier 2004 (19.01.2004)

Déposant

TEBRO S.A. etc

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Bureau international de l'OMPI
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Translation

PATENT COOPERATION TREATY
PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference VALS 882 B PCT	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/EP2004/000346	International filing date (day/month/year) 19.01.2004	Priority date (day/month/year) 20.01.2003	
International Patent Classification (IPC) or national classification and IPC G06M 1/22, 1/04, 1/24			
Applicant TEBRO S.A.			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>4</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/000346

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:

international search (Rule 12.3 and 23.1(b))
 publication of the international application (Rule 12.4)
 international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished
 the description:
 pages 1-10 as originally filed/furnished
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____

the claims:
 nos. _____ as originally filed/furnished
 nos.* _____ as amended (together with any statement) under Article 19
 nos.* 1-19 received by this Authority on 10.11.2004 with the letter filed on 08.11.2004
 nos.* _____ received by this Authority on _____

the drawings:
 sheets 1/4-4/4 as originally filed/furnished
 sheets* _____ received by this Authority on _____
 sheets* _____ received by this Authority on _____

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

the description, pages _____
 the claims, nos. _____
 the drawings, sheets/figs _____
 the sequence listing (*specify*): _____
 any table(s) related to sequence listing (*specify*): _____

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages _____
 the claims, nos. _____
 the drawings, sheets/figs _____
 the sequence listing (*specify*): _____
 any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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1. Statement

Novelty (N)	Claims	6-16, 18, 19	YES
	Claims	1-5, 17	NO
Inventive step (IS)	Claims	13-16	YES
	Claims	1-12, 17-19	NO
Industrial applicability (IA)	Claims	1-19	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1. Reference is made to the following documents:

D1: GB-A-1 336 014 (METTOY CO LTD) 7 November 1973
(1973-11-07);

D2: WO 96/39337 A (SENETICS INC) 12 December 1996
(1996-12-12);

D3: WO 01/37909 A (HOERLIN ERNST; ERNST HOERLINS
INGENJOERSBYRAA (SE)) 31 May 2001 (2001-05-31).

2. New claims filed on 08.11.2004

2.1 The claims filed on 08.11.2004 add the following features to claim 1:

2.1.1 "..., and in that the indicator includes actuation means comprising two flexible elements having different degrees of flexibility, with the more flexible element allowing said rotary metering wheel to rotate at the start of the actuation stroke of the dispensing device, while the less

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

flexible element allows said actuation stroke to be continued following rotation of said metering wheel."

2.1.2 This amendment to claim 1 is contrary to the provisions of **PCT Article 34(2)(b)** because the addition of these features causes the subject matter of the application to be extended beyond the content of the application as filed. Indeed, this amendment is not supported by the description as originally filed. More precisely, on page 8, line 9, of the description, the expression "at least" applies to the expression "a flexible tab" and the expression "having two different degrees of flexibility" applies to the expression "two flexible portions". It follows that reference cannot be being made to "at least one drive element" as the amendment submitted on 08.11.2004 appears to suggest.

2.1.3 It follows that this amendment (i.e. the passage in point 2.1.1) has not been taken into consideration when establishing the international preliminary report. It should, therefore, be noted that the claims which are examined herein are the same as the claims which were filed originally.

3. **Novelty (PCT Article 33(2)):**

3.1 Document D1 describes (the references between parentheses apply to said document; see, in

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

particular, figures 1 and 2 and page 1, line 80 to page 2, line 33):

an indicator comprising a rotatable metering wheel (4) and a translatable member (8), which metering wheel comprises indicating means (figure 1) in cooperation with a display opening (12) in said translatable member (8) and a hollow profile member (7) in engagement with a projection (9) on said translatable member (8), wherein the shape of said hollow profile member (7) is such that at least some revolutions of said rotatable metering wheel (4) cause translation of said translatable member (8), thereby modifying the position of said translatable member (8) in relation to said metering wheel (4).

In a fluid-dispensing device, an indicator of this kind is suitable for indicating the number of doses already dispensed or still to be dispensed.

It follows that the subject matter of **claim 1** is not novel.

3.2 Similarly, the subject matter of **claims 2-5 and 17** is disclosed in D1, page 2, lines 14 and 28-34 and is, consequently, not novel.

4. Inventive step (PCT Article 33(3)):

4.1 Even if the applicant has doubts with regard to

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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the above arguments concerning novelty (see point 3.1), it should be noted that the subject matter of claim 1 cannot, under any circumstances, be considered to be inventive.

4.2 **Dependent claims 6-12** do not appear to contain any features which, in combination with the features in any one of the claims to which they refer, might define subject matter that fulfils the PCT requirement of inventive step. For example, in order to solve the same problems, document D2 (see figures 8-11 and page 39, line 25 to page 44, line 19) describes, in general, a system for counting the doses already dispensed and, in particular, the features in claims 6-12.

4.3 Document D3 describes (the references between parentheses apply to said document; see, in particular, figures 4, 5 and 7 and page 11, lines 4-31):

a fluid-dispensing device (1) comprising a fluid container (4), a dispensing member (see figure 7) such as a pump or a valve mounted on said container (4), and a dose indicator (2).

Regardless of its size, such a device is not suitable for indicating a large number of doses.

In D1, this problem is solved by virtue of an indicator corresponding to the one in claim 1, as mentioned in point 2.1.

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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A person skilled in the art, faced with this problem, would use the teaching of D1 in combination with that of D3 and thereby arrive at the subject matter of claim 18.

As a result, the subject matter of **claim 18** does not involve an inventive step.

4.4 **Claim 19** does not appear to contain any features which, in combination with the features in claim 18, might define subject matter that fulfils the PCT requirement of inventive step.

5. **The features in claim 13 are, in combination with the features in the claims on which it is dependent, novel and inventive, for the following reasons:**

The indicator actuation means comprise a flexible tab consisting of two portions having different degrees of flexibility, and the actuation tooth on the indicator wheel is supported on the first more flexible portion of said tab, with the result that the indicator can be actuated during the first part of the dose dispenser stroke and the dispenser nevertheless has sufficient freedom of movement to enable a dose to be dispensed properly.

These features are not described or suggested in the available prior art.

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

5.1 Claims 14-16 are dependent on claim 13 and, as such, therefore also fulfil the PCT requirements of novelty and inventive step.